

Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Duty to Consult; Notice to Consumers

Title 16 Sections Affected: Amend 16 Cal. Code Reg. § 1707.2
Add 16 Cal. Code of Regs § 1707.6

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above sections, but is updated to include the following information.

Recommendations and comments received during the 45-day public comment period from May 27, 2011 to July 11, 2011 were considered by the Board at its July 26-27, 2011 meeting. The Board's responses to the comments received are detailed under "Summary of Comments Received During the 45-Day Comment Period." After reviewing the comments received during the 45-day comment period and also those received on July 27, 2011 at the Regulation Hearing, the Board directed staff to take all steps necessary to complete the rulemaking process, authorize the Executive Officer to make any non-substantive changes, and authorize staff to send out a 15-day modified text notice that includes changes discussed and voted on at the meeting. The board further directed that if no adverse comments were received during the 15-day comment period, authorize the Executive Officer to adopt the regulations at Sections 1707.2 and 1707.6 as noticed in the modified text Notice.

The following changes were made to the specific text, which are deemed to be non-substantive:

In the Authority and Reference for Amended Section 1707.2, a reference to section 1707.5 of Title 16 of the California Code of Regulations was removed.

In the Authority and Reference for new Section 1707.6, a reference to section 1707.5 of Title 16 of the California Code of Regulations was removed.

The Underlying Data identified relevant meeting materials and minutes from the Legislation and Regulation Committee Meeting held on July 19, 2010. The date was in error, as the committee met on October 19, 2010. Thus, relevant meeting materials and minutes from the October 2010 meeting of the Legislation and Regulation Committee are provided in the Underlying Data (item 6.B.).

Local Mandate:

None.

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of comments or testimony indicating adverse economic impact regarding this rulemaking proposal.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to the affected persons than the proposed regulation.

Summary of Comments Received During the 45-Day Comment Period (Objections or Recommendations/Responses):

The board received the following comments during the 45-day public comment period:

Comment from Amy Brotzman

Ms. Brotzman stated that the pharmacy “should provide notice to patients that they may have an interpreter for all 12 languages” and she further stated her objection to using a “threshold” of languages. She added that smaller groups of individuals who speak non prevalent languages may be in need of [this type] of information at a greater level.

Board Response

The board views Ms. Brotzman’s comments to be in support of the board’s proposed regulation, as the board did include in the proposed text a requirement that every pharmacy shall post or provide a notice, in a place conspicuous to and readable by a prescription drug consumer, a notice using the following words:

Point to your language. Interpreter services will be provided to you upon request at no cost.

The board’s regulation further specifies that the above text be repeated in at least 12 specified languages. (See proposed text at 16 CCR 1707.6(c).)

Comment from Senator Ellen M. Corbett

Senator Corbett commented on the board’s patient-centered prescription drug label requirements, which were promulgated in a separate rulemaking as a result of legislation she authored in 2007. (Note: SB 472 amended Business and Professions Code 4076.5 to establish patient-centered prescription labels. Subsequent to enactment, the board promulgated regulations at 16 Cal. Code of Regs § 1707.5 to establish requirements for

patient-centered prescription drug labels.)

#1 - Senator Corbett states that current law does not require pharmacies to post notices informing consumers of their rights, or to translate those notices into languages other than English, and that the board's pending proposal would implement such requirements.

Board Response #1

Existing statute at Business and Professions Code Section 4122(a) requires every pharmacy to prominently post a notice provided by the board. The requirement's first became effective in 1996. Subdivision (d) of this section exempts from the requirement to post a Notice to Consumers a hospital pharmacy that is accessible only to hospital medical staff and personnel. Statute requires that the board's notice contain information related to

- the availability of prescription price information, the possibility of generic drug product selection,
- the type of services provided by pharmacies, and
- a statement describing patient's rights relative to the requirements imposed on pharmacists pursuant to Section 733

This proposal at 16 CCR § 1707.6(b) would specify the text of the board's notice .

This proposal also would require a pharmacy to provide notice to a prescription drug consumer, as specified, that they are entitled to interpreter services upon request at no cost to the consumer. The proposal also specifies that this notice be printed in twelve non-English languages, as specified. (See proposed 16 CCR § 1707.6(c).)

#2 - Senator Corbett thanks the board for requiring pharmacies to provide translated notices about the rights of patients to have interpreter services and larger font in at least 12 languages. She states this is a "good first step" to implementing the goals of SB 472.

Board Response #2

The board appreciates the comments of Senator Corbett and also believes that its proposal is a "good first step" to amending its Notice to Consumers to include information related to the patient-centered prescription label requirements.

The board did not, however, include a requirement in its proposal to require pharmacies to provide translated notice in at least 12 languages about the patient's right to request larger font on their prescription label.

The board's proposal at 16 CCR § 1707.6(b) does specify that the "Notice to Consumers" poster – or other format or display methodology, if so requested and approved by the board – include the statement

"You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font."

However, the board's proposal does not require that the statement above be translated into at least 12 languages.

The board considered this comment at its Board Meeting held July 27, 2011, and did not modify the text of the regulation in response.

#3 - Senator Corbett urges the board to add language to the regulation that would establish an objective threshold for when a pharmacy must provide notices in additional languages. Specifically, Senator Corbett requests that the regulation state "that a pharmacy must provide a notice translated into any language the Board determines, based upon the most recent United States census data, is spoken by at least 20,000 residents in California."

Board Response

The board infers that this comment is in response to the language proposed at 16 CCR 1707.6 (c).

During discussions of the rulemaking, prior to issuance of the Initial Notice, the board considered how many languages the statement specified in subdivision (c) should be printed. At its March 2011 Board Meeting at which the board voted to initiate the rulemaking, the board reviewed and discussed the Department of Managed Health Care's Threshold Languages by Health Plan document as well as the Department of Health Service's MMCD All Plan Letter 02003, which specifies the cultural and linguistic contractual requirements for Medi-Cal managed care. At that time, the board voted to explicitly state in its proposed regulation the (12) languages which would be required to be printed. At its July 2011 Board Meeting, and following the Regulation Hearing held July 27, 2011, the board reviewed the comments of Senator Corbett and others, and determined that the proposed regulation – which specified twelve languages in which the text specified in Subdivision (c) shall be printed – was clear and specific. The board did not modify the text of the regulation in response to this comment.

Comment from Caroline B. Sanders, MPP, California Pan-Ethnic Health Network (CPEHN)

#1 - On behalf of CPEHN, Ms. Sanders commended the board for requiring California pharmacies to provide translated notices about the rights of patients to no-cost interpreter services and larger, 12-point font size for prescription drug labels. Ms. Sanders stated that offering these notices is a "good first step" and that proper notification is essential for all patients to understand how to take their medication effectively and safely.

Board Response #1

The board appreciates Ms. Sanders' comments and also believes that its proposal is a "good first step" to amending its Notice to Consumers to include information related to the patient-centered prescription label requirements.

The board's proposal at §1707.6(a) specifies that every pharmacy shall prominently post a "Notice to Consumers" – the text of which is specified at §1707.6(b). The "Notice to Consumers" language (specified in §1707.6(b)) includes a statement regarding the patient's

right to ask for and receive prescription drug labels in 12-point font. The board did not include in its proposal a requirement that this “Notice to Consumers” be translated.

The board’s proposal also specified at §1707.6(c) that every pharmacy shall have a second notice at each pharmacy counter where dangerous drugs are dispensed or furnished, a notice with the language below. It is this notice that indicates that the text shall be repeated (translated) in at least 12 languages.

Point to your language. Interpreter services will be provided to you upon request at no cost.

The board considered this comment at its Board Meeting held July 27, 2011, and did not modify the text of the regulation in response.

#2 - Ms. Sanders urged the board to adopt a language threshold (rather than a set list of languages in which to offer translated notices) to allow the state to reach the broadest number of patients while reflecting California’s changing demographics. Ms. Sanders asked the board to amend proposed 16 CCR §1707.6(c) to state that notices

“be translated into languages spoke by at least 20,000 or more limited-English-proficient Californians.”

Ms. Sanders states that the amended language would add just five more languages (French, Portuguese, Hindi, Japanese and Thai) to the list of 12 languages as proposed by the board, which is reflective of the U.S. Census Bureau, 2007-2009 American Community Survey 3-Year Estimates. She further states that adopting the recommended language would increase consumer protections and improve the health, safety and well-being of consumers.

Board Response #2

During discussions of the rulemaking, prior to issuance of the Initial Notice, the board considered how many languages the statement specified in subdivision (c) should be printed. At its March 2011 Board Meeting at which the board voted to initiate the rulemaking, the board reviewed and discussed the Department of Managed Health Care’s Threshold Languages by Health Plan document as well as the Department of Health Service’s MMCD All Plan Letter 02003, which specifies the cultural and linguistic contractual requirements for Medi-Cal managed care. At that time, the board voted to explicitly state in its proposed regulation the (12) languages which would be required to be printed. At its July 2011 Board Meeting, and following the Regulation Hearing held July 27, 2011, the board reviewed Ms. Sanders’ comments and did not modify the text of the regulation in response. The board’s discussion reflected that the statement *“at least 20,000 or more limited-English-proficient Californians”* lacked specificity and would not provide pharmacies with the clarity needed to know what languages they would be required to provide translated statements in.

Comment from Paul E. Huntzinger, RPh

Mr. Huntzinger comments on proposed §1707.6(c) that – while well intentioned – the board’s regulation would likely increase the likelihood of dispensed medications as well as increase the incidence of consumer misinformation [*sic*]. He states that there are not enough translators available that are appropriately trained in pharmaceutical terminology that could provide appropriate counseling.

Board Response

The board does not agree with Mr. Huntzinger’s comment. The board’s proposal does not implement a new requirement on a pharmacy to provide interpretive services to patients; rather, the board’s current proposal amends the “Notice to Consumers” so that patients are aware of a pharmacy’s current requirement to provide interpretive services. The board believes that if a consumer knows that they have the right to have the information on their prescription drug label interpreted in a specified language, that the consumer will be more likely to ask for those services; and upon receiving such services, the consumer will better understand important information regarding their medication, how and when to take it, what it does, and other information.

Current regulation at 16 CCR §1707.5(d) requires each pharmacy to have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in 16 CCR §1707.5(a) in the patient’s language, and further states that the pharmacy – at minimum – shall provide interpretive services in the patient’s language, if interpretive services in such language are available. This section further specifies when those services shall be available and the method by which those services shall be provided. The board’s current proposal at 16 CCR §1707.6(c) amends the board’s “Notice to Consumers” to provide the consumer with notice that they have the right to ask for interpretive services and receive important information regarding their prescriptions.

The board considered Mr. Huntzinger’s comments at its board meeting held July 27, 2011, and did not move to modify the text of the proposed regulation in response.

Comment from Luis Miguel, PhD, Advantpage

Dr. Miguel commented on the board’s requirement for pharmacies to provide translated notices about the rights of patients to no-cost interpreter services and larger, 12-point font size for prescription drug labels. He states that offering the notices in at least 12 different languages is a good first step and that proper notification of these rights is essential for all patients to understand how to take their medication effectively and safely.

Dr. Miguel states that the board should adopt a “language threshold” to include all languages spoken by at least 20,000 or more limited-English-proficient health consumers in order to reach the broadest number of patients and more accurately reflect California’s changing demographics.

Board Response

The board's proposal at §1707.6(a) specifies that every pharmacy shall prominently post a "Notice to Consumers" – the text of which is specified at §1707.6(b). The "Notice to Consumers" language (specified in §1707.6(b)) includes a statement regarding the patient's right to ask for and receive prescription drug labels in 12-point font. The board did not include in its proposal a requirement that this "Notice to Consumers" be translated.

The board's proposal also specified at §1707.6(c) that every pharmacy shall have a second notice at each pharmacy counter where dangerous drugs are dispensed or furnished, a notice with the language below. It is this notice that indicates that the text shall be repeated (translated) in at least 12 languages.

Point to your language. Interpreter services will be provided to you upon request at no cost.

During discussions of the rulemaking, prior to issuance of the Initial Notice, the board considered how many languages the statement specified in subdivision (c) should be printed. At its March 2011 Board Meeting at which the board voted to initiate the rulemaking, the board reviewed and discussed the Department of Managed Health Care's Threshold Languages by Health Plan document as well as the Department of Health Service's MMCD All Plan Letter 02003, which specifies the cultural and linguistic contractual requirements for Medi-Cal managed care. At that time, the board voted to explicitly state in its proposed regulation the (12) languages which would be required to be printed. At its July 2011 Board Meeting, and following the Regulation Hearing held July 27, 2011, the board reviewed Ms. Sanders' comments and did not modify the text of the regulation in response. The board's discussion reflected that the statement "*at least 20,000 or more limited-English-proficient Californians*" lacked specificity and would not provide pharmacies with the clarity needed to know what languages they would be required to provide translated statements in.

The board considered Dr. Miguel's comments at its board meeting held July 27, 2011, and did not move to modify the text of the proposed regulation in response.

Comments from Michael J. Negrete, PharmD, CEO, Pharmacy Foundation of California

#1 - Dr. Negrete asks if additional time could be built into the regulatory process to allow for consumer testing of the proposed language, to explore issues including health literacy, relative importance of various messages, etc. He expressed particular interest in studying specific text found in proposed 16 CCR § 1707.6(b). Dr. Negrete stated his basic concern is that the information proposed may not be presented in a manner that helps ensure consumers will see the text, read and understand it, understand its importance, and act upon the information. Dr. Negrete expressed an interest in securing grant funding to perform an evaluation of the language proposed, and then provide the board with suggestions for improvement of the proposed language.

Board Response #1

At the Regulation Hearing held July 27, 2011, the board expressed to Dr. Negrete its appreciation of the Pharmacy Foundation of California's interest to secure grant funding and subsequently conduct a study of the language at proposed § 1707.6(b). The board discussed the importance of providing consumers with an updated "Notice to Consumers"—one that incorporated information related to the patient's right to interpretive services and the patient's right to ask for larger font (typeface) on their prescription labels. The board discussed the frequency of its Board Meetings, the timeframe associated with a general rulemaking, and opportunities the board might have to consider any information that may be gathered during a study; however, the board concluded that that extending the time on the rulemaking would unduly delay action on the regulation and did not vote to delay the rulemaking to accommodate Dr. Negrete's comment. The board did state, however, that it would be interested in the study results, should the Pharmacy Foundation of California move forward to conduct such a study on the matter.

#2 - Dr. Negrete requested that the Notice to Consumers, as specified in proposed 16 CCR § 1707.6(b), include a statement clearly notifying consumers that pharmacists are required to provide them with a consultation on all new prescriptions. He suggested that the text "California law requires a pharmacist to speak with you every time you get a new prescription" be the first statement in the board's Notice to Consumers. During the Regulation Hearing conducted July 27, 2011, Dr. Negrete reiterated his suggestion to include this statement in the Notice to Consumers.

Board Response #2

Following the Regulation Hearing conducted on July 27, 2011, the board discussed Dr. Negrete's suggestion to modify the Notice to Consumers at proposed 16 CCR §1707.6(b) to include the statement "California law requires a pharmacist to speak with you every time you get a new prescription." Dr. Negrete stated that if a consumer knew it was the law for a pharmacist to consult a patient every time a new prescription was dispensed, the consumer would be more likely to accept the consultation. In response to this comment, the board voted to modify the proposed text at § 1707.6 (b) to include as the first sentence under "NOTICE TO CONSUMERS" the statement "California law requires a pharmacist to speak

with you every time you get a new prescription.” This modified language was noticed for public comment on July 28, 2011, and the 15-day public comment period concluded on August 12, 2011. The board did not receive any comments to this modified text.

Comment from Mike A. Podgurski, RPh

Mr. Podgurski asks if there is a chance of the language specifying the phrase “or similar” where the patient points to their language. He added that *[his pharmacy’s brochure]* is not exactly the same (as the proposed regulation).

Board Response

The board infers that Mr. Podgurski asks the board to consider modifying the text of proposed §1707.6(c) to allow for like or similar statements than what is specified in the board’s proposal.

*(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following **or similar** text:*

The board considered this comment at its Board Meeting held July 27, 2011, and did not modify the text of the regulation in response. The board felt the term “or similar” lacked specificity and would not impart a clear statement as to what would be required by the regulation.

Comment from Richard I. Sakai, PharmD, FASHP, FCSHP, Children’s Hospital Central CA

#1 - Dr. Sakai asks where the Notice to Consumers poster is to be posted in the hospital setting he described in his e-mail. He also asks if the hospital can request an exemption from the (proposed) regulation.

Board Response #1

Business and Professions Code Section 4122(a) specifies that in *every pharmacy* there shall be “prominently posted in a place conspicuous to, and readable by, prescription drug consumers, a notice provided by the board....” B&PC § 4112(d) specifies that the requirements of the section (to post the Notice to Consumers) “shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.”

While statute does provide an exception to a hospital pharmacy as specified in § 4122(d), the statute does not provide the board with the authority to “exempt” other pharmacies from the statutory requirement to prominently post the Notice to Consumers. Thus, if a hospital has an out-patient pharmacy, one that is accessible to patients and/or the public, that pharmacy must comply with Business and Professions Code Section 4122(a) and post the “Notice to Consumers” as required.

#2 – Dr. Sakai asks if physician offices that dispense medications are required to provide (these services) and if the physician is required to post the information to the consumer.

Board Response #2

Business and Professions Code Section 4122 specifies that ***in every pharmacy*** there shall be posted a notice by the board, as specified. Accordingly, only pharmacies licensed by the Board of Pharmacy are subject to the requirements of the board's regulations.

#3 – Dr. Sakai comments that the board did not reference English in the listing of languages provided in the board's proposed regulation.

Board Response #3

Business and Professions Code Section 11 specifies

"Writing includes any form of recorded message capable of comprehension by ordinary visual means. Whenever any notice, report, statement, or record is required by this code, it shall be made in writing in the English language unless it is otherwise expressly provided."

Because the board is required to produce the notice in English, it was not necessary to List the English language as one of the languages in which the notice in proposed § 1707.6(c) is translated.

#4 – Dr. Sakai states "Ironically, if you need interpretation in another language, how can one read the notice which is in English to understand these services are to be offered in other languages?"

Board Response #4

The board's proposal at §1707.6(c) specifies that every pharmacy shall provide or post a notice at each pharmacy counter where dangerous drugs are dispensed or furnished, that contains the text below. This section also specifies that the text shall be repeated (translated) in at least 12 languages. Thus, an individual will see the notice printed in English and re-stated in twelve additional languages, that "interpreter services" will be provided to them upon request.

Point to your language. Interpreter services will be provided to you upon request at no cost.

Comment from Peter Scalet

Mr. Scalet stated that the "religious exemption for filling a prescription" has been removed from the "Notice to Consumers," and he requests that this exemption be placed back in the notice.

Board Response – the Board’s current regulation at 16 CCR §1707.2(g) included the following statement, to which Mr. Scalet refers.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The board’s proposal at 16 CCR §1707.6(b) includes a statement that advises the patient that the pharmacy must provide any medicine or device legally prescribed for them, with certain exceptions. The notice also states that if a medicine or device is not immediately available, the pharmacy will work with the patient to help them get their medicine or device in a timely manner.

In crafting the language of proposed 16 CCR §1707.6(b), the board reviewed the current “Notice to Consumers” as well as the requirements of B&PC Sections 4122 and 733. Business and Professions Code Section 4122 requires that every pharmacy post a notice provided by the Board. That section states that the notice include a statement describing the **patient’s right** relative to the requirements imposed on a pharmacist pursuant to Section 733.

Business and Professions Cod Section 733 requires a licentiate to dispense drugs and devices upon a lawful order or prescription, unless specified circumstances exist. One of the circumstances described (at B&PC 733(b)(3)) specifies that a licentiate may decline to dispense a drug or device if the licentiate refuses on ethical, moral, or religious grounds; that the licentiate has previously notified his or her employer of the drug or class of drugs to which he or she objects; and other requirements. Likewise, Section 733(f) of the Business and Professions Code states that the “notice to consumers” that is required by B&PC 4122 shall include a statement that describes the **patient’s rights** relative to the requirements of the section.

The board believes that its proposal fulfills the requirements of B&PC Sections 4122 and 733, in that the proposed “Notice to Consumers” at 16 CCR §1707.6(b) advises **the patient** that if a medicine or device is not immediately available, the pharmacy will work with them to help them get their prescribed medicine or device in a timely manner. The board believes the statement included at 16 CCR 1707.6(b) [see below] does represent a statement that describes patients’ rights relative to the requirements of B&PC Section 733.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

The board considered Mr. Scalet’s comments at its Board Meeting held July 27, 2011, and did not move to modify the text of the proposal to place the text from the existing Notice to Consumers (at 16 CCR 1707.2) into the current proposal.

Comments Received at the July 27, 2011 Regulation Hearing

The board conducted a regulation hearing on July 27, 2011, in Sacramento, California. Oral comments received at that meeting are summarized below.

Comments from Dr. Michael Negrete

#1 - Dr. Negrete expressed his concern with the proposed text at § 1707.6(b) *[see below]*, as the proposed regulation does not allow flexibility of other language which may be more effective or more easily understood by consumers. He states the proposed text is written to be read at the 12th –14th grade level, and that the average adult has a reading level between the 7th – 9th grades. He stated there is a clear disconnect between the proposed language and what the average adult understands. He further stated that the language may prevent people from coming up with better copy that would have a more meaningful impact for the consumer. He referenced his written comments in that the Pharmacy Foundation of California has offered to secure grant funding and conduct a study of the language for the purpose of improving the readability and understanding of the language in the notice. He stated that he would like to see some flexibility so that individuals could submit to the board for approval other language that could be used on the poster.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. As the pharmacist if you have any questions.

Board Response

The board appreciates Dr. Negrete's comments. However, the board feels that the text provided at proposed § 1707.6(b) is clear and that the phrases are reflective of the language used on the current Notice to Consumers. The board feels that the language used on the Notice to Consumers must be consistent throughout all pharmacies.

At the Regulation Hearing held July 27, 2011, the board expressed to Dr. Negrete its appreciation of the Pharmacy Foundation of California's interest to secure grant funding and subsequently conduct a study of the language at proposed § 1707.6(b). The board discussed the importance of the Notice to Consumers and the need to update the content to also include information related to larger font sizes and interpretive services. In consideration of the time limits for a regular rulemaking, and also in consideration of the frequency that Board Meetings are held, the board concluded that that extending the time on the rulemaking would unduly delay action on the regulation. Thus, the board did not move to delay the rulemaking to accommodate Dr. Negrete's comment/offer. The board did state, however, that it would be interested in the results, should the Pharmacy Foundation of California move forward to conduct such a study on the matter.

#2 - Dr. Negrete stated that he would like to see a clear, explicit statement included in the Notice to Consumers regarding a pharmacist's duty to consult. He stated that if the consumer sees that the pharmacist is required by law to provide a consultation, the consumer would think there is a good reason for the law and would be more inclined to make sure that they got a consultation.

Board Response #2

The board discussed Dr. Negrete's suggestion and agrees that the Notice should contain the most important information for consumers.

In response to Dr. Negrete's comment, the board voted to modify the proposed text at § 1707.6 (b) to include as the first sentence under "NOTICE TO CONSUMERS" the statement "California law requires a pharmacist to speak with you every time you get a new prescription." This modified language was noticed for public comment on July 28, 2011, and the 15-day public comment period concluded on August 12, 2011. The board did not receive any comments to this modified text.

#3 – Dr. Negrete spoke in support of a requirement to require pharmacies to post the Notice to Consumers – for the benefit of the consumers, but also for the benefit of the pharmacy staff. He added that it is equally important for the staff in the pharmacy to remain aware of the information in the Notice to Consumers. He said his organization has found that individuals (pharmacy staff) who are the least trained have the highest turnover and that ensuring that the Notice to Consumers is posted in an obvious place makes sure that staff are aware of – and reminded of – the requirements. He added that staff who know the requirements also will provide a greater level of accountability to make sure the consumer receives the information they need.

Board Response #3

The board agrees with the supportive comments offered by Dr. Negrete.

#4 – Dr. Negrete expressed concern with the proposed language in 1707.6 (a) (see below), stating that pharmacies think it is okay to post the Notice to Consumers in a waiting room adjacent to the pharmacy. He said that that in the current age of electronic prescribing (telephonic and electronic refills), a lot of people don't enter the pharmacy until it is time to pick up their prescription and that there is often no need to wait in a waiting area. He added that even if a consumer does need to wait for a prescription, the consumer often does shopping, and they would not see the Notice to Consumers if it were posted in a waiting area.

Dr. Negrete said he would like to see some clarity of the phrase in the first sentence at proposed § 1707.6(a) "in a place conspicuous to and readable by a prescription drug consumer, ..." to include any place the in the pharmacy where the prescription may be dropped off and/or picked up, including a drive-thru.

Board Response #4

The language proposed at § 1707.6(a) reflects statutory language found at Business and Professions Code § 4122(a). The board believes that the pharmacy needs the flexibility to determine the location that is “conspicuous to, and readable by” prescription drug consumers.

While conducting inspections at pharmacies, inspectors will view the placement of the Notice to Consumers to determine if the pharmacy is compliant with existing laws and regulations. If the inspector feels the Notice to Consumers posted in the pharmacy is not compliant with statutes or regulations, the inspector may identify corrective action(s) to be taken. The board considered the recommendation to modify the text at proposed § 1707.6(a) but felt that the proposed text was clear and sufficient. Thus, the board did not modify the text of the proposed regulation in response to this comment.

#5 – Dr. Negrete commented on the proposed regulation text at § 1707.6(c) where a separate notice regarding interpreter services is required related to interpretive services. He stated that he would not want that to be part of the larger Notice to Consumers (as required by § 1707.6(b)) as there is already a lot of information on the larger poster.

Board Response #5

The board appreciates Dr. Negrete’s comments. The notice required by proposed § 1707.6(c) is separate from the Notice to Consumers described in proposed § 1707.6(b).

#6 – Dr. Negrete would like the board to consider some type of requirement for mail order pharmacies. He added that if the information is important enough to be posted in thousands of pharmacies all over California, he would like to see some like requirement for the mail order pharmacies so that they also could impart the important information in the Notice to Consumers to patients that receive their prescriptions through the mail.

Board Response #6

Non-resident (mail order) pharmacies are required to comply with Business and Professions Code § 4122, which requires every pharmacy to prominently post a notice provided by the board, and further specifies the content to be provided in that notice. Section 4122(a) also specifies that “A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.” Section 4122 of the Business and Professions Code applies to every pharmacy licensed by the board, including non-resident pharmacies.

Should the board receive a complaint related to any pharmacy that may not be posting the Notice to Consumers currently required by § 1707.2 and as proposed at § 1707.6(b), the board is authorized to investigate and take appropriate action, including administrative or disciplinary action, against the pharmacy.

Comment from Paige Talley, California Pharmacists Association

Ms. Talley expressed concern with the proposed text at § 1707.6(b) in that the “right of conscious” language in the existing poster [§1707.2 (g), see below] is not contained in the new Notice to Consumers. She recommends that the “right of conscious” language be added to the proposed language at § 1707.6(b).

“This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.” [16 CCR § 1707.2(g)]

Board Response

The Notice to Consumers is for the consumer’s benefit – to convey important information relative to the rights of the patient, not the pharmacist. Business and Professions Code § 4122(a) specifies the information that shall be included in the notice, to include “a statement describing the *patients’ rights* relative to the requirements imposed on a pharmacist pursuant to Section 733.” The board believes that the language specified at proposed § 1707.6(b) does clearly convey the *patient’s right* to obtain a prescription drug or device that has been legally ordered for the patient. Thus, the board did not vote to modify the language in response to the comment.

Comments from Carrie Sanders, California Pan-Ethnic Health Network

#1 - Ms. Sanders referenced her written comments submitted to the board during the 45-day comment period as they relate to the proposed text at § 1707.6(c); specifically, the number of languages in which the following text shall be printed: “Point to your language. Interpreter services will be provided to you upon request at no cost.” She stated that the Department of Insurance identifies fourteen (14) different languages. She asked the board to clarify why the specific twelve languages were included, i.e., show how the board came up with the list of twelve languages.

Ms. Sanders stated that CPEHN would like to see the regulation specify that the statement “Point to your language,” contained in proposed § 1707.6(c) be printed in any language in which groups of 20,000 or more Californians speak. She stated that she would like to see the board add the five languages she identified in her letter (French, Portuguese, Hindi, Japanese and Thai) to the twelve (12) languages currently specified at proposed § 1707.6(c).

Board Response #1

Following the regulation hearing, the board discussed each comment received during the 45-day comment period and at the regulation hearing. The board reflected on its March 30, 2011 Board Meeting, at which the board extensively discussed which languages it would specify in the regulation and subsequently voted to initiate the rulemaking process. The board reflected that it decided to utilize the twelve languages listed Department of Health Services MMCD All Plan Letter 02003 dated June 7, 2002 and that – rather than incorporate into the regulation a document by reference – it would list the twelve languages identified in the MMCD All Plan Letter in the board’s regulatory proposal. The board discussed that in

the future it can re-visit the languages that are listed and make changes through the regulatory process. The board determined that to move forward and not unduly delay the regulation, it would move forward with the current proposed text (specifying 12 languages) and not modify the list of languages in response to the comment. However, the board did reiterate that it would re-visit the list of languages at a future time.

#3 – Ms. Sanders stated that CPEHN agrees with the board’s statement (included in the Informative Digest) that the Notice to Consumers does not place additional requirements on pharmacies. She referenced the requirements of Title VI of the Civil Rights Act of 1964.

Board Response #3

The board appreciates Ms. Sanders’ comment.

Comment from Mary Staples, National Association of Chain Drug Stores

Ms. Staples spoke in support of the regulation and urged the board to adopt the text as proposed. She added that the NACDS would hate to see the rule delayed any longer. She stated that the current Notice to Consumers is inadequate and they would like to see the rule, as proposed, adopted.

Board Response

The board appreciates the comments offered by Ms. Staples in support of the regulation, as proposed.

Comments from Steven Gray, PharmD, JD, Kaiser Permanente

#1 – Dr. Gray stated that Kaiser echoes the sentiments of the NACDS (see comment above) and that Kaiser urges the board to move forward with its proposal. Dr. Gray spoke in support of the proposed text at § 1707.6(a) which indicates that a pharmacy can use the standardized poster provided by the board or – as an alternative to a printed notice, the pharmacy also or instead display the notice on a video screen, as specified. Dr. Gray, however, suggested that the wording be re-arranged or modified. He believes the text – as proposed – allows the Executive Officer (or committee of the board) to approve another format or display methodology of the (printed) Notice to Consumers, but the requirements for a video (e.g., the screen being at least 24 inches; the text remains on screen for a minimum of 60 seconds, etc.), are not subject to alteration. He recommends that the language be modified so that the Executive Officer (or committee of the board) is authorized to not only approve another format or display methodology of the printed Notice to Consumers, but also the technical aspects or sequencing of the video. He stressed that the goal is communication – not to just put a poster up – and, as the industry develops, he would like to see the regulation allow for innovation.

Board Response #1

The board appreciates Dr. Gray's comments in support of the regulation text at § 1707.6(a) and agreed that proposed §1707.6(a) should be modified to provide the Executive Officer (or committee of the board) the authority to grant approval of another format or display methodology as it relates to a video display of the Notice to Consumers.

In response to the comment/recommendation, the board voted to modify the text of the proposal to add the following sentence to the end of proposed § 1707.6(a):

"The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval."

This modified language was noticed for public comment on July 28, 2011, and the 15-day public comment period concluded on August 12, 2011. The board did not receive any comments to this modified text.

#2 – Dr. Gray commented on the regulation where "every pharmacy" shall prominently post the Notice to Consumers. He commented on closed-door pharmacies and hospital pharmacies where the public does not frequent – and stated that, when board inspectors visit these facilities, the inspectors ask "where are the posters?" Dr. Gray stated this situation could possibly be addressed through board policy or the language could be modified to include a statement that every pharmacy "open to the public" would be required to post the Notice to Consumers.

Board Response #2

Business and Professions Code Section 4122(a) specifies that in *every pharmacy* there shall be "prominently posted in a place conspicuous to, and readable by, prescription drug consumers, a notice provided by the board...." B&PC § 4112(d) specifies that the requirements of the section (to post the Notice to Consumers) "shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel."

The phrase "every pharmacy" proposed § 1707.6(a) mirrors that which is specified in B&PC 4122(a). While statute does provide an exception for a hospital pharmacy as specified in § 4122(d), the statute does not provide the board with the authority to "exempt" other pharmacies from the statutory requirement to prominently post the Notice to Consumers.

#3 – Dr. Gray commented on the text of the Notice to Consumers proposed at § 1707.6 (b) – the paragraph beginning with "This pharmacy must provide any medicine or device legally prescribed for you, . . ."

Dr. Gray spoke in support of the comments offered by Paige Talley as to the “right of conscious” language in the existing poster (§1707.2 (g), see below) and that the old language is not contained in the new Notice to Consumers. He stated that Kaiser believes it would be beneficial for the public to be made aware of the pharmacist’s right to decline to fill a prescription based on his or her right of conscious. He said he believes the instances are infrequent when a pharmacist exercises this right, but those situations can be emotional. He added that the current language (below) is better than no language at all.

“This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.” [16 CCR § 1707.2(g)]

Board Response #3

The Notice to Consumers is for the consumer’s benefit – to convey important information relative to the rights of the patient, not the pharmacist. Business and Professions Code § 4122(a) specifies the information that shall be included in the notice, to include “a statement describing the *patients’ rights* relative to the requirements imposed on a pharmacist pursuant to Section 733.” The board believes that the language specified at proposed § 1707.6(b) does clearly convey the *patient’s right* to obtain a prescription drug or device that has been legally ordered for the patient. Thus, the board did not vote to modify the language in response to the comment.

#4 – Dr. Gray spoke to text of the Notice to Consumers proposed at § 1707.6 (b) – the paragraph beginning with “This pharmacy must provide any medicine or device legally prescribed for you, . . . If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.”

Dr. Gray commented on the proposed text, taken in context with a pharmacist’s existing duty to consult. He described Kaiser’s policy where – with specific drugs that are deemed to be extremely dangerous to a person’s health – Kaiser will not dispense a medication if the patient refuses a consultation.

Board Response #4

The board appreciates Dr. Gray’s comments and acknowledged the pharmacist’s requirement to dispense lawfully prescribed or ordered drugs or devices, unless the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient’s medical condition. (B&PC § 733(b))

#5 – Dr. Gray spoke in support of the text at proposed § 1707.6(c) which specifies twelve languages that a specified phrase must be printed/translated. He stated that the pharmacy needs to know specifically how to comply with the regulation and that Kaiser supports the language, as written, which identifies the languages that the phrase must be printed in. He

added that the proposed regulation specifies a *minimum* number of languages, and that a pharmacy may print the phrase in more/additional languages if the pharmacy chooses.

Board Response #5

The board appreciates Dr. Gray's comments and agrees that the proposed regulation (which indicates twelve specific languages) is clear and specific.

Letter Comments from Havard Skaggs, California Commission on Aging

#1 - Through a letter transmitted to the board via e-mail, Mr. Skaggs, on behalf of the California Commission on Aging, commented that the CCoA has concerns regarding provisions authorizing the posting of the board's "Notice to Consumers" on video, adding that the 60-second display requirement may be inadequate for an individual with limited reading skills or poor eyesight. The CCoA asks that the board require – even when video notification is available – that a printed hard copy be simultaneously posted in an easily visible and unobstructed location.

Board Response #1

Business and Professions Code Section 4122 requires every pharmacy to post the notice to consumers provided by the board, as specified. Through its current rulemaking, the board felt it was useful and appropriate to allow for additional formats or display methodologies of its "Notice to Consumers" and allow pharmacies to utilize existing and emerging technologies to display the "Notice to Consumers" to its patients/customers. In its proposal, the board specifically proposed that "as an alternative to a printed notice" a pharmacy would be able to utilize a video display of the notice. Existing law (at B&PC 4122) currently allows a pharmacy to provide a written receipt that contains the required information on the notice be provided to consumers as an alternative to posting the notice in the pharmacy. With regard to Mr. Skaggs' comment that a 60-second display is inadequate, the board's proposal at 16 CCR §1707.6(a) specifies **a minimum of** a 60-second display; in practice, the notice *could* be displayed for longer than 60 seconds.

#2 - The CCoA commented that the board's notification could be confusing to persons who are not familiar with font sizes. The CCoA recommended that written notification posted at pharmacies be printed in the referenced font sizes for greater clarification.

The CCoA included an example in their letter:

"You have the right to ask for and receive from any pharmacy
prescription drug labels printed in: 12 point font or 14 point
font."

Board Response #2

Current regulation at 16 CCR § 1707.5(a)(1) specifies that specified information on a prescription label be printed in at least 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface. The board intended in its proposed language at 16 CCR

§ 1707.6(b) which states “You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font” to let consumers know that they could request prescription drug labels in 12-point font. There is no existing or proposed requirement to provide a prescription drug label in 14-point font. Also, in the existing regulation at 16 CCR 1707.5(a)(1), the term “typeface” is utilized. The board felt in its initial proposal that using the term “font” was easy to understand and reflected the use of plain English.

Summary of Comments Received During the 15-Day Comment Period for Modified Text (Objections or Recommendations/Responses):

The board did not receive any comments regarding the specific modified text that was made available for the 15-day comment period. The board did receive two letters (Scalet, Staggs) that were duplicate copies of comments submitted during the 45-day comment period, but the comments were not considered to be responsive to the modified text made available.